Quality control project in ST elevation myocardial infarction

STEMI registration in Belgium

The importance of ischemic time delay on mortality

Background

Acute heart attacks are a major healthcare problem with still high mortality and morbidity rates.
The major goal in the treatment of AMI is the rapid restoration of blood flow and myocardial perfusion in the infarct zone and this can be obtained either by pharmacological approach (fibrinolysis) or by mechanical approach (primary Percutaneous coronary intervention, PCI). Primary PCI has been shown to offer a substantial benefit over fibrinolysis (e.g. 30% reduction in mortality and re-infarction rate) at least if the procedure is performed by highly experienced operators and within 90 minutes after the first medical contact. As availability of PCI centres is limited, regional transfer protocols are important and should allow transfer of high risk patients (e.g. Killip class >1) to hospital with PCI facilities.
Previous international studies have emphasised the importance of time delay between onset of symptoms and initiation of reperfusion therapy (=ischemic time). In those studies a correlation could be documented between time delay and in hospital mortality. Also time between admission and initiation of reperfusion therapy has been show to be an important risk factor (door-to-balloon time)
At this moment no data are available on these time issues in the Belgian STEMI patients.

Purpose

The college of cardiology together with the Belgian working group on acute cardiology (BIWAC) set up a minimal data base registry for ST elevation myocardial infarction in all Belgian centres with a minimum acute cardiac care program A in order to

1. describes time related issues with regard to the management of STEMI
2. assess the relationship between time delay and in hospital mortality
3. identify whether time delay remains an independent factor after correction for other prognostic factor (such as age, Killip Class)

Methods:

Collection of data is carried out by electronic web-based registry that is governed by an independent software company specialised in electronic data capture solutions (Lambda-plus- website: http://www.lambdaplus.com).
A number of baseline characteristics for each patient is included which allows to stratify the patients according to a previous validated TIMI risk score: age, gender, Killip class, collapse with cardiopulmonary resuscitation (CPR), history of coronary artery disease (CAD) or peripheral artery disease (PAD), location of infarction. Especial attention is given to following time related issues:
Total ischemic time: time from the onset of symptoms until the initiation of reperfusion therapy (either thrombolysis or PCI).
Door-to-needle time: time from diagnosis of STEMI until initiation of thrombolysis
Door-to-balloon time: time from diagnosis of STEMI until first balloon inflation

In addition the register includes data about reperfusion strategy (primary PCI, thrombolysis,...) transfer issues and data about in hospital mortality.

Access to the registry was available in the first part of 2007 only to the members of the steering committee and from 1/7/2007 access was extended to all Belgian hospitals with acute cardiac care program. Over time there was a gradual increase in the enrolment of STEMI patients. For the present study we report the data of 2526 STEMI patients that were included from 1/1/2007 until 1/5/2008 in a total of 80 hospitals

Results:

The distribution of total ischemic time in Belgium is depicted in figure 1.
Almost 60% of all patients received reperfusion therapy within 4h.
In fig 2 the proportion of patients with total ischemic time >4h is shown for the 10 regions in Belgium

Fig 1

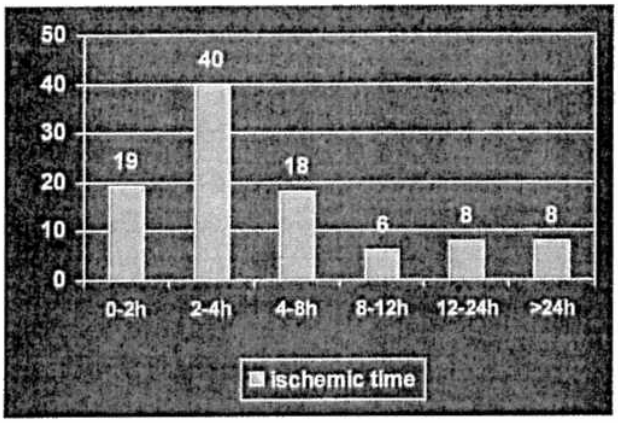
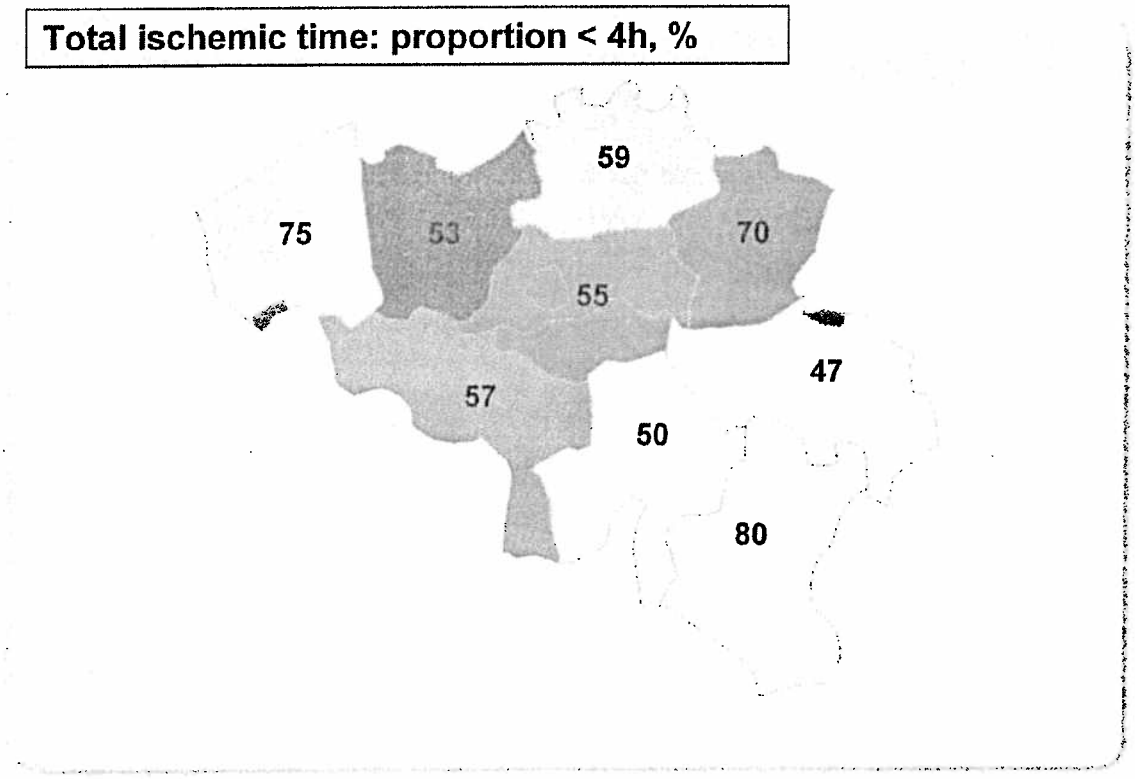


Fig 2



In table 1 the time delay between diagnosis and treatment is shown for both primary PCI (=door-to-balloon time) as for thrombolysis (=door-to-needle time)
80% of the patients scheduled for primary PCI received their treatment within the range of international recommendations (door-to-balloon < 90 min).
50% of the patients scheduled for thrombolysis received their treatment within the range of international recommendations (door-to-needle < 30 min).

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Table 1: door-to-balloon/needle time

	<30 min	30-60 min	60-90 min	90-120 min	>120 min
Prim PCI (n=1939)	17%	36%	24%	9%	11%
Trombolysis (n=368)	50%	20%	6%	3%	8%

The overall in hospital mortality in the study population is 6.6%

The relation between total ischemic time and in hospital mortality is depicted in fig 3
There is a clear trend to higher mortality with higher ischemic time delay ($p<0.0001$)
This relation is stronger for thrombolysis ($p<0.0001$) than for PCI ($p=0.02$) see fig 4.
Absolute mortality figures in the late (>8h) thrombolysis group should be interpreted cautiously because of small numbers.

Figure 3: in hospital mortality versus total ischemic time

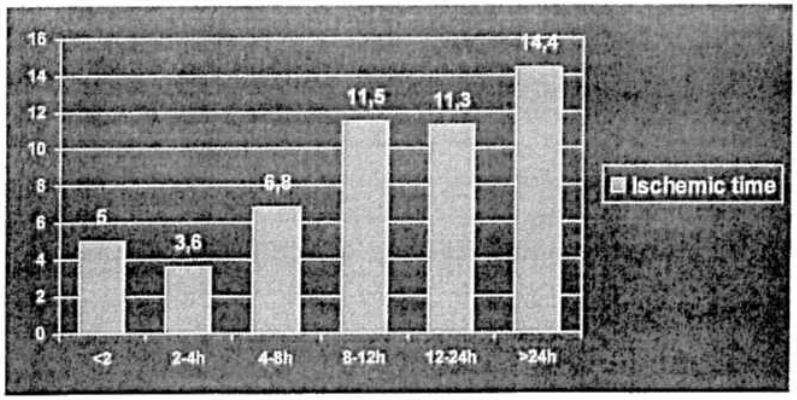
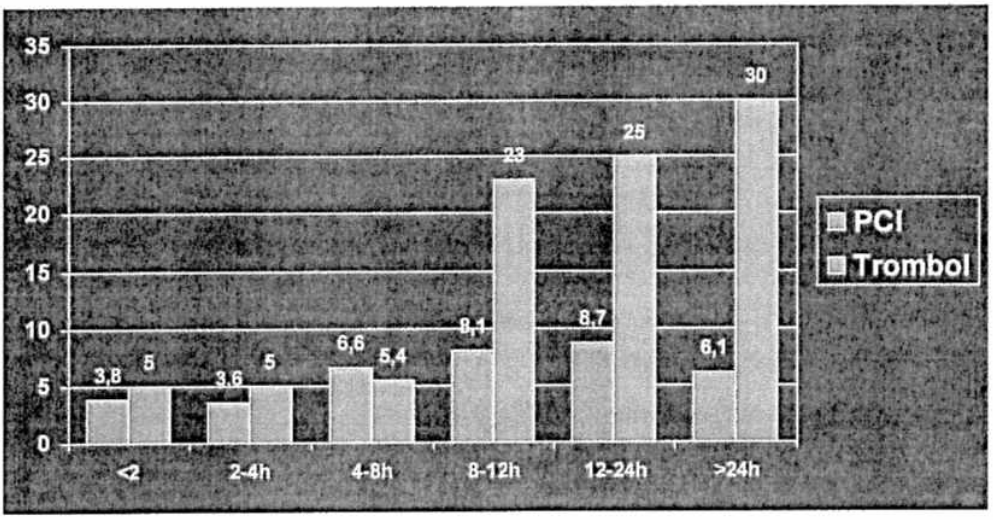


Figure 4: mortality and total ischemic time for PCI versus thrombolytic patients



With regard to door-to-needle time, no significant correlation could be found between in-hospital mortality and the time for diagnosis to initiation of thrombolysis. In contrast, a significant correlation was found between door-to-balloon time and in hospital mortality: Patients receiving primary PCI <90 min had a much lower mortality than those receiving PCI >90 min after the diagnosis: 4.7 versus 6.4 p=0.001.

Finally we performed logistic regression analysis to identify the independent determinants for in hospital mortality. As shown in table 2 total ischemic time remains an independent prognostic factor with OR of 2.1. Door to balloon/needle time was not independently related with outcome (p=0.46)

	P value	OR (95%CI)
Killip > 1	<.0001	12 (7 - 20)
CPR	<.0001	5.3 (3-8)
age	<.0001	1.04 (1.03-1.07)
No-PCI	0.002	2.5 (1.4 - 5)
Ischemia>4h	0.003	2.1 (1.4-3.5)
PAD	0.006	2.0 (1.2-4)

Conclusion and Discussion

The present registry is the first prospective registry enrolling patients from both PCI and no-PCI centres.
The overall in hospital mortality is 6.6 % and compares well with current European ACS surveys. In the present study total ischemic time delay was independently related to mortality. Patients with time delay >4h had a more than two time increase in death as compared to those with time delay <4h: **10% versus 4%.**

Total ischemic time delay can be subdivided into delay from onset of pain until diagnosis and delay from diagnosis to treatment. With regard to delay from diagnosis to treatment (door-to-balloon/needle time), the Belgian data are in general good, although some improvement is still needed to reach the international goals. Good performance is most likely the reason why the door-to-balloon/needle time turned out not to be an independent prognostic factor in our analysis. Hence, the time between onset of pain and diagnosis (=prehospital delay) is the most important determinant of the total ischemic time. Sensibilisation of the population is therefore crucial in order to decrease further the mortality of STEMI patients. For this reason, we organised in close collaboration with the Cardiologische Liga a sensibilisation campaign in 2007 to inform people about the warning signs of a heart attack (e.g. prolonged chest pain) and about the need to call for urgent medical help once they experience these alarming signs.

We hope that repetitive efforts to sensitize the population will result in a decrease in total ischemic time delay and in subsequent lower mortality rate. We will closely follow these data in our STEMI registry.

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Background

Acute heart attacks are a major healthcare problem with still high mortality and morbidity rates.

The major goal in the treatment of AMI is the rapid restoration of blood flow and myocardial perfusion in the infarct zone and this can be obtained either by pharmacological approach (fibrinolysis) or by mechanical approach (immediate coronary angiography and coronary dilatation of the occluded infarct artery, the so called primary PCI). Primary PCI has been shown to offer a substantial benefit over fibrinolysis (e.g. 30% reduction in mortality and re-infarction rate) at least if the procedure is performed by highly experienced operators and within 90 minutes after the first medical contact. For this reason rapid transfer to hospital with PCI facilities is mandatory especially for patients with large infarctions.

Thanks to applications of those more effective reperfusion strategies we can expect, according to the data of randomized trials, that the in hospital mortality should be less than 5% but, in daily practice, mortality remains above 10%. Possible reasons for these gaps between reality and theory are still largely unknown but may include poor implementation of reperfusion strategies, long treatment delays, and poor public awareness of heart attack. In addition data from RIZIV/ENAMI suggest a substantial variation in mortality among the Belgian hospitals possibly related to differences in patient population and/or patient treatment. A more complete knowledge of those factors and of outcome in patients with acute myocardial infarction is a prerequisite to improve the prognosis of heart attack in Belgium.

Purpose

The college of cardiology together with the Belgian society of Cardiology and its working group on acute cardiology want to set up a minimal datd base registry for ST elevation myocardial infarction in Belgian centres in order to identify more accurately factors of mortality in STEMI patients in Belgium and to help hospitals to adhere to guidelines by providing on-line benchmark reports to all individual centres

Electronic Registry (https//www.biwacstemi.be)

A number of baseline characteristics for each patient will be included which should allow to stratify the patients according to a previous validated TIMI risk score. In addition the register will include data about reperfusion strategy, transfer issues and data about in hospital mortality. (see example in attachement)
The registry will be governed by an independent software company specialised in electronic data capture solutions (Lambda-plus- website: http://www.lambdaplus.com).

Realisation program

A multi-step program has been designed to implement this database in all Belgian centres with facilities for acute cardiac care. (A-B1-B2-B3 hospitals)

2006

1. **Pilot project (Q1-Q2 2006):**
   collection of the mimimal data base of one patient per centre
   a total of 55 centres of the 110 Belgian hospitals replied
   The average risk score was 4.3 and the average mortality was 4%
   About 1/3 of the patients received thrombolysis and 1/3 were transferred to PCI centre for primary/rescue PCI

2. **Realisation of prototype of web-based registry (Q3-Q4 2006).**

   Based upon the evaluation of this pilot project the final version of the e-CRF was made and the prototype was tested.

2007 planning

3. Initiation and installation of e-CRF in a limited number of centres (Q1 2007)

4. Implementation of web-based registry in all Belgian centres (Q2-Q4 2007)
   Organisation of regional meetings to explain the aim and practical organisation of the minimal data base

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PILOT PROJECT : MINIMAL DATABASE

ST-VERHEFFING HARTINFARCT REGISTRATIE

Ziekenhuisidentificatie: **Naam ziekenhuis:** .....
Ziekenhuis met PCI mogelijkheden: JA / NEE

Patiëntenkarakteristieken bij opname

Opnamedatum: .....
Leeftijd: ..... **geslacht:** man - vrouw
Gewicht: > 67kg vs < 67 kg
Cardiovasculaire voorgeschiedenis:
Ischemisch hartlijden - Perifeer vaatlijden
Arteriele hypertensie - Diabetes mellitus
Killip Klasse: 1 (geen hartfalen) – 2 – 3 - 4 (shock)
Cardio-pulmonale reanimatie: JA / NEE
Bloeddruk : <100 vs >100 mmHg
Hartritme: <100 vs >100 slagen/min
ECG : anterior MI / non-anterior MI / LiBB

Reperfusiebehandeling binnen de eerste 24 uur:

Totale ischemietijd: (tijd vanaf begin klachten tot behandeling)
<3u / 3-6u / 6-12u / 12-24u
Reperfusiebehandeling:
Trombolyse / Primaire PCI
Rescue PCI* / Gefaciliteerde PCI **
Geen reperfusiebehandeling : reden: .....

Prehospitale trombolyse : JA / NEE
Transport naar PCI centrum: JA / NEE

Klinisch Verloop

In-hospitaal mortaliteit (tot één maand na het infarct): JA / NEE

Opmerkingen/suggesties over de registratie

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